IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, *et al.*, Plaintiffs, *ex rel.* Scarlett Lutz, *et al.*, Plaintiffs-Relators, v. Berkeley Heartlab, Inc., *et al.*, Defendants.	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2458-RMG) **ORDER and OPINION**

This matter is before the Court on a motion by BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson (collectively, "the BlueWave Defendants") to exclude the United States' proffered expert testimony of Kathleen McNamara. (Dkt. No. 448.) Defendant Latonya Mallory has filed a motion joining the BlueWave Defendants' motion to exclude the testimony of Kathleen McNamara. (Dkt. No. 449.) The United States has filed a response in opposition. (Dkt. No. 471.) For the reasons set forth below, the motions to exclude are denied.

I. Background and Relevant Facts

The Government has filed a complaint in intervention against the BlueWave Defendants and Latonya Mallory alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the False Claims Act ("FCA"), 42 U.S.C. § 3729. (Dkt. No. 75.) The alleged FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2015. The Government has alleged that Defendants violated the FCA when

they engaged in multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. For example, the Government alleges that Defendants offered and facilitated the payment of processing and handling ("P&H") fees to physicians to induce referrals in violation of the AKS and FCA.

The United States has proffered the expert testimony of Kathleen McNamara regarding the fair market value and commercial reasonableness of the P&H fees by HDL and Singulex to physicians or physician practices. Those P&H fees were paid pursuant to written P&H Fee agreements between the laboratories and physicians or their practices. BlueWave marketed HDL and Singulex lab testing services to physicians pursuant to written sales agreements.

II. Legal Standard - *Daubert*

Under Rules 104(a) and 702 of the Federal Rules of Evidence, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The trial court must ensure that: (1) "the testimony is the product of reliable principles and methods"; (2) "the expert has reliably applied the principles and methods to the facts of the case"; and (3) the "testimony is based on sufficient facts or data." Fed. R. Evid. 702. "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," *Daubert*, 509 U.S. at 592-93, and whether the expert has "faithfully appl[ied] the methodology to facts," *Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006). To make this determination, courts consider several factors including: (1) "whether a theory or technique . . . can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the theory or technique has

garnered "general acceptance." *Daubert*, 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). However, these factors are neither definitive nor exhaustive, *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015) (quoting *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003)), and "merely illustrate[] the types of factors that will bear on the inquiry," *Hassan*, 742 F.3d at 130 (quoting *Crisp*, 324 F.3d at 266).

Courts have also considered whether the "expert developed his opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or through "research they have conducted independent of the litigation," *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand), and whether experts have "failed to meaningfully account for . . . literature at odds with their testimony." *McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010).

Rule 702 also requires courts "to verify that expert testimony is 'based on sufficient facts or data.'" *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Id.* The court may exclude an opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* "The proponent of the [expert] testimony must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The Court is mindful that the *Daubert* inquiry involves "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence," *id.*, and "the trial court's role as a gatekeeper is not intended to serve as a replacement

for the adversary system." *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013), (citing Fed. R. Evid. 702 advisory committee's note). On the other hand, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading,' it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *Fultz*, 591 F. App'x at 227 (quoting *Cooper*, 259 F.3d at 199).

III. Discussion

A. McNamara's Qualifications

The BlueWave Defendants argue that McNamara has no experience in the lab industry so should not be allowed to give an opinion on the Fair Market Value ("FMV") of transactions executed pursuant to laboratory agreements. (Dkt. No. 448 at 13.) Defendants do not otherwise challenge McNamara's qualifications to provide FMV and commercial reasonableness opinions, and the Court finds that McNamara is qualified to provide both based on her comprehensive qualifications and experience. (Dkt. No. 448-1 at 2-3, 55-57.) The record shows that McNamara has been found qualified by other Courts to provide FMV and commercial reasonableness opinions in the healthcare context, specifically with regard to physician compensation and services. The Court therefore finds McNamara qualified to provide opinions on the FMV and commercial reasonableness of payments to physicians and physician practices based on her knowledge and experience. In this case, that includes payments to physicians made by laboratories.

B. McNamara's FMV Analysis

1. Definition of FMV

The BlueWave Defendants argue that McNamara's FMV analysis is unreliable primarily because she used an improper definition of FMV. They argue that McNamara inappropriately concluded that a FMV analysis cannot take into account the volume or value of referrals because

she (1) relied on the FMV definition in the Stark provisions, 42 U.S.C. § 1395nn, governing physician self-referral for Medicare and Medicaid Patients even though the Government has not pleaded a Stark violation (Dkt. No. 448 at 5); (2) claimed to rely on the valuations standards of the American Society of Appraisers' Business Valuation Standards and the American Institute of Certified Public Accountants' Standards for Valuation Services, even though neither of these standards explicitly requires exclusion of the volume or value of referrals from FMV calculations; (3) inappropriately relied on a provision of the personal services safe harbor provision of the AKS even though defendants did not plead reliance on a safe harbor and compliance with a safe harbor is not mandatory for compliance with the AKS (Dkt. No 448 at 6); (4) inappropriately relied on the 1992 Thornton advisory opinion letter which does not "mandate the exclusion of consideration of referrals" (Dkt. No. 448 at 6); (5) inappropriately relied on administrative guidance from the Office of Inspector General (Dkt. No. 448 at 7); and (6) inappropriately relied on the June 25, 214 Special Fraud Alert issued by the Office of Inspector General of the Department of Health and Humans Services that was not available to Defendants during the time they paid P&H fees.

The BlueWave Defendants argue that McNamara's definition of FMV, which excludes consideration of the value or volume of referrals, creates "absurd results." (Dkt. No. 448 at 9-10.) The Defendants seem to have conflated two separate issues. McNamara explained in her deposition that she concluded the *business arrangement* between the laboratories and physicians was designed to "take into account" the value and volume of referrals because the number of referrals impacted the amount of compensation.

McNamara did not include the value or volume of referrals in her calculation of the FMV of P&H fees in the marketplace because doing so would defeat the purpose of an analysis

designed to determine whether payments to physicians in this case were higher than the FMV for the services actually performed and so may have disguised remuneration intended to induce referrals[1], a practice that is illegal under the AKS. *See United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 97 (3d Cir. 2009) ("[W]here one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation."); *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006). In AKS cases, the fact finder may infer that payments were intended to be kickbacks based on evidence that the recipient was grossly overpaid for any legitimate services he provided).

The BlueWave Defendants provide no support for their argument that a FMV analysis should include the value or volume of referrals besides citing the lack of explicit statutory language excluding consideration of these factors. The two cases defendants rely on do not support their conclusion. (Dkt. No. 448 at 8.) First, neither case supports the consideration of the value or volume of referrals in a FMV analysis. As the Government noted, both cases rely on *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045 (N.D. Ill. 2002), regarding the appropriate FMV standard in AKS cases. *Obert-Hong* directly contradicts Defendants' argument: "We note that fair market value here may differ from traditional economic valuation formulae. Normally, we would expect the acquisition price to account for potential revenues from future referrals. Because the Anti-Kickback Act prohibits any inducement for those referrals, however, they must be excluded from any calculation of fair value here." 211 F. Supp. 2d at 1049 n.2. As the Court has explained in previous orders, there is

[1] The AKS "does not criminalize referrals for services paid for by Medicare or Medicaid—it criminalizes knowing and willful acceptance of remuneration in return for such referrals." *U.S. ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 697 (N.D. Miss. 2012).

no one-size-fits-all approach to performing an FMV analysis, but the Court finds McNamara's cost-based approach that excludes the volume and value of referrals to be reliable in this case.

2. Cost Approach to FMV Analysis

The BlueWave Defendants argue that McNamara ignored a market approach and income approach to FMV and critically ignored comparable lab-to-lab P&H fee agreements in her FMV analysis (Dkt. No. 448 at 12.) Defendants do not dispute that the cost approach to FMV is widely accepted, and Defendants' own literature refers to the cost approach as an accepted methodology. (Dkt. No. 448-17 at 10; 448-18 at 20.) Further, Defendants do not argue that a reliable FMV analysis requires the use of two or three separate methodologies or that the market or income approach would be more reliable in the context of this case. For her part, McNamara explained why she concluded that why the market and income approach were not appropriate in this case. (Dkt. No. 448-1 at 18, 39.) For these reasons, the Court finds that McNamara's reliance on the cost-based approach to be a reliable methodology.

3. Figures used in FMV Analysis

To determine the FMV of P&H services, the record shows that McNamara took into account (1) the time needed to perform P&H tasks; (2) the type of personnel who perform P&H tasks; (3) the labor cost associated with the P&H tasks, including wages and benefits; (4) the office space needed to perform P&H tasks; and (5) the equipment and supplies needed to perform P&H tasks. (Dkt. No. 448-1 at 21–22.) McNamara explained in detail the foundation for the figures she used in her analysis. (*Id.* at 21–38.) The BlueWave defendants do not dispute that McNamara executed the cost approach properly. They disagree only with the figures McNamara used to represent the cost of office space, cost of labor, and centrifuge time.

a. Office Space

The BlueWave Defendants argue that McNamara's use of 20 square feet to represent the office space necessary to perform phlebotomy/venipuncture services was subjective and so should be excluded. McNamara explained in her report what equipment was needed to perform these services and why she though 20 square feet was sufficient to house the equipment and personnel. The time/motion study that HDL commissioned from Exponent estimated that 100 square feet would be needed, but the author of the report acknowledged that only a portion of this space would be needed to perform P&H services. (Dkt. No. 471-5 at 52.) For these reasons, the dispute over McNamara's use of 20 square feet is not grounds for exclusion of her testimony.

b. Labor

The BlueWave Defendants claims that McNamara arbitrarily used the 75th percentile of hourly wage rates in her calculation of the cost of labor for phlebotomists and medical assistants and arbitrarily made the decision to divided labor time equally among registered nurses, licensed practical nurses, medical assistants, and phlebotomists. (Dkt. No. 448 at 13-4.) The record shows that the Exponent analysis Defendants rely on used an average hourly rate based on data from the U.S. Bureau of Labor Statistics. (Dkt. No. 547-4 at 9.) McNamara's use of the 75^{th} percentile instead of the mean inures to defendants' benefit because the Government attests (and Defendants did not contest) that the mean hourly rate would have been lower than the 75th percentile.

McNamara also explained her reasons for dividing up time equally among medical assistants, licensed practical nurses, registered nurses, and phlebotomists. (Dkt. No. 448-1 at 23-24.) McNamara's opinion that a FMV analysis based on labor costs of personnel paid more than medical assistants and phlebotomists would improperly inflate P&H costs was supported by evidence in the record that HDL and Singulex would provide phlebotomists (not higher paid

personnel) when asked to provide personnel to collect, process, and handle blood specimens. (Dkt. No. 471 at 15.) McNamara also accounted for the costs of hiring higher-paid personnel in her more conservative scenario as compared to her more likely scenario (Dkt. No. 448-1 at 47), and to the extend Defendants disagree with her weighting of the various types of personnel (although they have provided no factual basis for disputing her method), they may do so on cross examination.

c. Centrifuge Time

The BlueWave Defendants note that McNamara allocated zero minutes for centrifuging time while Mallory assigned 15 minutes to the same task. That Mallory came to a different conclusion about the time assigned to centrifuging does not render McNamara's analysis unreliable. McNamara explained that she assigned zero minutes to centrifuging to avoid double counting labor time and costs because personnel perform other tasks while the centrifuge is running. (Dkt. No. 448-1 at 27.) The author of the Exponent time-motion study commissioned by HDL conceded in her deposition that this would likely be appropriate to avoid double-counting. (Dkt. No. 471-5 at 42.)

C. McNamara's Commercial Reasonableness Opinion

The BlueWave Defendants argue that a commercial reasonableness opinion is not relevant to this case because commercial reasonableness is not a requirement under the AKS statute. (Dkt. No. 448 at 15). The Government argues that evidence that the P&H fee arrangements were not commercially reasonable absent the value of referrals is relevant to (1) Defendant's intent that the fees be used to induce future referrals; (2) rebutting Defendants' claim that they had valid business reasons for entering the P&H arrangements; and (3) rebutting Defendant's advice of counsel defense because the defense relies on letters from counsel that discuss the personal services safe harbor and commercial reasonableness requirement.

The Court agrees with the Government. The United States may rely on requirements of the personal services save harbor where Defendants have asserted as a defense the good faith reliance on advice of counsel when that advice indicated that the fees paid to physicians in this case were FMV, commercially reasonable, and in compliance with the personal service safe harbor. To qualify under the safe harbor provision, the compensation for services must "not [be] determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties." 42 C.F.R. § 1001.952(d)(5); *See United States v. TEVA Pharms. USA, Inc.*, Civ. A. No. 13-3702, 2016 WL 750720, at *18 (S.D.N.Y. Feb. 22, 2016) (finding that allegations supported inference that payments were "not consistent with fair market value" because physicians received payments only if they generated sufficient referrals); *United States ex rel. Singh v. Bradford Med. Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 634 (W.D. Pa. 2010) ("[T]he compensation received by the doctors from [defendant] is not fair market value because it was determined in a manner that takes into account the volume or value of referrals.").

The BlueWave Defendants also argue that McNamara's commercial reasonableness analysis is deficient because she did not consider labs similar to HDL and Singulex and physicians who perform services similar in scope to the physicians who allegedly received kickbacks in this case. (Dkt. No. 448 at 16-17.) A commercial reasonableness analysis does not require the Government's expert witness to do more than determine whether a transaction for a specific service would be commercially reasonable between any type of laboratory and any type of physician. The Defendants have not given any reason why a general practitioner ordering a test would find it commercially reasonable to pay a laboratory more for a test than, for example, a cardiovascular specialist.

D. Information Under Seal

The BlueWave Defendants claim that it is "patently unfair" that they have not been able to "fully explore McNamara's past Government work experience," including Medicare and Medicaid fraud cases she has worked on that are under seal. Defendants claim this is a basis for excluding McNamara as a recalcitrant witness. (Dkt. No. 448 at 21.) Defendants have cited no reason they believe information about McNamara's work on these other cases would be relevant to this case, and the Government asserts that McNamara has not relied on any work from those cases in the present case. That these cases remain under seal is not evidence of McNamara's recalcitrance.

E. Legal Conclusions

The BlueWave Defendants claim that McNamara proffers legal conclusions and interpretations throughout her report, listing several representative examples of her legal conclusions regarding intent. (Dkt. No. 488 at 18-20.) As explained in the Court's order excluding the BlueWave's expert Daniel Mulholland, expert testimony about the correct interpretation of legal standards and the ultimate issue of Defendants' scienter or intent is inadmissible. In any event, the Government has represented that it does not intend to have McNamara espouse any legal conclusions or interpretations at trial. (Dkt. No. 471 at 20.)

Defendants also object to McNamara's proffered testimony regarding the "facts involving HDL and Singulex paying P&H fees prior to the time they obtained FMV analyses." (Dkt. No. 448 at 20.) While McNamara conceded that an FMV valuation need not be obtained prior to entering into a service agreement, the Government asserts that these facts are relevant to her opinion that Defendants procured FMV analyses in order to justify or validate their practices after the fact. (Dkt. No. 448-1 at 18-21.) McNamara says this information is relevant because if a valuator is instructed that its task is to support the client's compensation practices, as the

Government alleged Mallory instructed Exponent to do, the valuator must take steps to independently validate the data and assumptions provided by the client. The Government argues that McNamara should be able to explain why she was cautious about relying on Defendants' data or assumptions, particularly if she is cross-examined about her reasons for rejecting certain data that she found unreliable.

The Court will not allow the Government to elicit testimony from McNamara about the timing of Defendants' procurement of an FMV analysis because that information is not relevant to her commercial reasonableness or FMV opinion (both of which this Court has found are based on McNamara's qualifications and experience) and has the potential to mislead the jury about the legal requirements for obtaining a FMV analysis, and, in turn, lead to improper testimony about Defendants' scienter and intent. However, if Defendants attempt during cross-examination to show that McNamara's failure to use the same data Defendants used is indicative of some improper intent, bias, or animus on her part, McNamara will be allowed to testify that the timing of the FMV analysis procured by defendants was relevant to her decision not to consider those figures.

IV. Conclusion

For the reasons set forth above, the motions filed by the BlueWave Defendants and Latonya Mallory to exclude the expert testimony of Kathy McNamara (Dkt. Nos. 448, 449) are denied.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

August 22, 2017
Charleston, South Carolina